

Amendments to the Claims:

Please amend Claims 1 and 21 to read as follows. All claims pending, including those unchanged by the present amendment, are reproduced below for the convenience of the Examiner. This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 1. (currently amended) A homogeneous pharmaceutical composition for
2 topical administration comprising:
3 at least 5% by weight, based on the total weight of the composition, of a
4 piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof;
5 an acid in an amount to substantially completely solubilise the
6 piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof, wherein the acid is
7 a mineral acid selected from the group consisting of hydrochloric acid, sulphuric acid, nitric acid,
8 and phosphoric acid, or an organic acid selected from the group consisting of citric acid, acetic
9 acid, succinic acid, maleic acid, benzoic acid, lactic acid and mixtures thereof;
10 a solvent selected from water and/or a lower alcohol;
11 a co-solvent selected from one or more of the group consisting of aromatic and
12 polyhydric alcohols; ~~wherein when the co-solvent includes propylene glycol, it is~~ present in an
13 amount of less than approximately 10% by weight;
14 wherein the final product of the homogeneous pharmaceutical composition is
15 selected from the group consisting of a solution, lotion, ointment, mousse, a foam that breaks
16 with shear, spray, aerosol, shampoo, conditioner, gel, cream and paste.

1 2. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the acid is added in an amount sufficient to provide an apparent
3 pH to the composition of approximately 7.0 or less.

1 3. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the piperidinopyrimidine derivative or pharmaceutically
3 acceptable salt thereof is present in an amount of from approximately 5 to 25% by weight, based
4 on the total weight of the homogeneous pharmaceutical composition.

1 4. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 3, wherein the piperidinopyrimidine derivative or pharmaceutically
3 acceptable salt thereof is present in an amount of approximately 7.5 to 12% by weight, based on
4 the total weight of the homogeneous pharmaceutical composition.

1 5. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the piperidinopyrimidine derivative or pharmaceutically
3 acceptable salt thereof is minoxidil or a salt thereof.

1 6. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 2, wherein the acid provides to the composition an apparent pH in the range
3 of approximately 5.0 to 7.0.

1 7. (Canceled)

1 8. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 2, wherein the acid includes acetic or lactic acid.

1 9. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the composition includes water and ethanol in a range of
3 approximately 1:1 to 1:3 by volume.

1 10. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the co-solvent includes benzyl alcohol.

1 11. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the composition includes water and benzyl alcohol wherein the

3 benzyl alcohol is in an amount of approximately 40 to 100% by weight based on the total weight
4 of the co-solvent system.

1 12. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the water is present in an amount no greater than approximately
3 60% by weight based on the total weight of the co-solvent system.

1 13. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the co-solvent system includes an alkylene glycol.

1 14. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 13, wherein the alkylene glycol is selected from one or more of the group
3 consisting of glycerol, 1,3-butylene or propylene glycol.

1 15. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the acid is present at a level that provides at least 0.01 Normal
3 acid.

1 16. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the acid is present in an amount equal to or greater than the
3 amount of the piperidinopyrimidine derivative in Normal amounts.

1 17. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the composition includes water and ethanol in a range of
3 approximately 9:1 to 1:9 by volume.

1 18. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 5, wherein the piperidinopyrimidine derivative or pharmaceutically
3 acceptable salt thereof is a minoxidil salt.

1 19. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 18, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

1 20. (previously presented) A homogeneous pharmaceutical composition
2 according to Claim 1, including
3 approximately 5 to 12% by weight, based on the total weight of the composition,
4 of a minoxidil or a minoxidil acid salt;
5 approximately 88 to 95% by weight of a solvent composition including
6 approximately 10 to 70% by weight of ethanol, approximately 2.5 to 85% by weight of benzyl
7 alcohol; and
8 less than 10% by weight, propylene glycol.

1 21. (currently amended) A method for the treatment of hair loss and related
2 indications in humans, comprising the steps of:
3 providing a homogeneous pharmaceutical composition for topical administration
4 having at least 5% by weight, based on the total weight of the composition, of a
5 piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof;
6 an acid in an amount to substantially completely solubilise the
7 piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof, wherein the acid is
8 a mineral acid selected from the group consisting of hydrochloric acid, sulphuric acid, nitric acid,
9 and phosphoric acid, or an organic acid selected from the group consisting of citric acid, acetic
10 acid, succinic acid, maleic acid, benzoic acid, lactic acid and mixtures thereof;
11 a solvent selected from water and/or a lower alcohol;
12 a co-solvent selected from one or more of the group consisting of aromatic and
13 polyhydric alcohols; ~~wherein when the co-solvent includes propylene glycol, it~~
14 ~~is~~ present in an amount of less than approximately 10% by weight; and
15 applying topically to the human scalp a therapeutically or prophylactically
16 effective amount of the homogeneous pharmaceutical composition.

1 22. (previously presented) A method according to Claim 21, wherein the
2 piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof is minoxidil or a
3 minoxidil salt.

1 23. (previously presented) A method according to Claim 22, wherein the
2 minoxidil salt is minoxidil acetate or minoxidil lactate.

1 24. (previously presented) A method according to Claim 21, wherein the
2 homogeneous pharmaceutical composition includes
3 approximately 5 to 12% by weight, based on the total weight of the composition,
4 of a minoxidil or a minoxidil acid salt;
5 approximately 88 to 95% by weight of a solvent composition including
6 approximately 10 to 70% by weight of ethanol, approximately 2.5 to 85% by weight of benzyl
7 alcohol; and
8 less than 10% by weight, propylene glycol.

1 25. (Canceled)